Summary of Safety and Effectiveness
R3 XLPE Anteverted Liners
Smith & Nephew, Inc.

K102370

Contact Person and Address
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Date of Summary: January 18, 2011

JAN 19 2011

Name of Device: R3 XLPE Anteverted Liners
Common Name: Acetabular System
Device Classification Name and Reference: 21 CFR 888.3358 Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis
Device Class: Class II
Panel Code: Orthopaedics/87 MBL

Device Description
Subject of this Abbreviated Premarket Notification are R3 XLPE Acetabular Liner line additions in an anteverted liner option. Anteverted liners modify the face opening of the acetabular liner component. The subject devices are intended to be used in conjunction with existing R3 Acetabular Shells, and they are intended to articulate against appropriately sized, existing Smith & Nephew femoral heads. They are manufactured from XLPE material and will initially be offered in inner diameters of 32 and 36mm and outer diameters of 48-72/74mm.

R3 XLPE Acetabular Liners have previously been cleared for market under premarket notifications K070756 and K092386 in liner options of 0°,0° lateralized +4mm, 20°, and 20° lateralized +4mm. The subject R3 XLPE Anteverted Liners are very similar to the R3 XLPE 20° lateralized +4mm Acetabular Liners cleared under K070756. The differences are described below.

- The face of the acetabular liner has been changed by 20° to re-orient the opening face of the liner relative to a given shell orientation when necessary
- Four vents have been added to the locking detail of the subject R3 XLPE Anteverted Liners.

Similar face changing liners have also been cleared for market by DePuy Orthopaedics, Inc. under premarket notification K062148.

Intended Use
Hip components are indicated for individuals undergoing primary and revision surgery where other treatments or devices have failed in rehabilitating hips damaged as a result of trauma or noninflammatory degenerative joint disease (NIDJD) or any of its composite diagnoses of osteoarthritis, avascular necrosis, traumatic arthritis, slipped capital epiphysis, fused hip, fracture of the pelvis, and diastrophic variant.

Hip components are also indicated for inflammatory degenerative joint disease including rheumatoid arthritis, arthritis secondary to a variety of diseases and anomalies, and congenital dysplasia; treatments of nonunion, femoral neck fracture and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques; endoprosthesis, femoral osteotomy, or Girdlestone resection; fracture-dislocation of the hip; and correction of deformity.

Performance Data

Performance testing has been conducted for the subject devices in accordance with the guidance titled "Guidance Document for Testing Acetabular Cup Prostheses," dated May 1995. Range of motion, attachment loads, fatigue properties, and cyclic wear, degradation, and corrsion have been evaluated. A review of the testing has demonstrated that there are no new issues related to the safety or effectiveness of the subject devices.

Clinical data was not needed to support the safety and effectiveness of the subject device.

Substantial Equivalence Information

The subject R3 XLPE Anteverted Liners are substantially equivalent to the predicate devices listed in the table below. Giving consideration to the device modifications described in the Device Description section, no changes have been made to the overall design philosophy, intended use, and material choices when compared to the predicate acetabular liners.

Manufacturer	Description	Submission Number	Clearance Date
Smith & Nephew, Inc.	Reflection 3 Acetabular System	K070756	6/6/07
Smith & Nephew, Inc.	R3 Multi-Hole Shells and 36mm XLPE Acetabular Liners	K092386	11/3/09
Smith & Nephew, Inc.	CoCr and Oxinium Femoral Heads and R3 XLPE Liners	K093363	1/26/10
DePuy Orthopaedics, Inc.	DePuy Pinnacle AltrX Acetabular Cup Liner	K062148	10/24/06

Conclusion

As previously noted, this Abbreviated 510(k) Premarket Notification is being submitted to request clearance for the R3 XLPE Anteverted Liners. Based on the similarities to the predicate devices and a review of the testing, the devices are substantially equivalent to acetabular liners currently marketed under K070756, K092386, K093363, and K062148.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Smith & Nephew, Inc.
% Ms. Megan Bevill
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1450 Brooks Road
Memphis, Tennessee 38116

Re: K102370

JAN 19 2011

Trade/Device Name: R3 XLPE Anteverted Liners
Regulation Number: 21 CFR 888.3358
Regulation Name: Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis
Regulatory Class: Class II
Product Code: MBL
Dated: January 12, 2011
Received: January 14, 20111

Dear Ms. Bevill:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K102370

Device Name: R3 XLPE Anteverted Liners

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The Reflection 3 Acetabular System is for single use only and is intended for cementless use.

Prescription Use X (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for M. Mulkerrin

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K102370